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EXAMINER: WOODWARD, M

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DATE MAILED: 06/22/94

This is a communication from the examiner in charge of your application.
COMMISSIONER OF PATENTS AND TRADEMARKS

☒ This application has been examined ☒ Responsive to communication filed on 7/8/93 ☐ This action is made final.

A shortened statutory period for response to this action is set to expire 3 month(s), — days from the date of this letter.
Failure to respond within the period for response will cause the application to become abandoned. 35 U.S.C. 133

Part I THE FOLLOWING ATTACHMENT(S) ARE PART OF THIS ACTION:

1. ☒ Notice of References Cited by Examiner, PTO-892.
2. ☐ Notice of Draftsman's Patent Drawing Review, PTO-948.
3. ☐ Notice of Art Cited by Applicant, PTO-1449.
4. ☐ Notice of Informal Patent Application, PTO-152.
5. ☐ Information on How to Effect Drawing Changes, PTO-1474.
6. ☐ _____.

Part II SUMMARY OF ACTION

1. ☒ Claims 60-66 are pending in the application.
   Of the above, claims _____ are withdrawn from consideration.
2. ☒ Claims 1-59 have been cancelled.
3. ☐ Claims _____ are allowed.
4. ☒ Claims 60-66 are rejected.
5. ☐ Claims _____ are objected to.
6. ☐ Claims _____ are subject to restriction or election requirement.
7. ☒ This application has been filed with informal drawings under 37 C.F.R. 1.85 which are acceptable for examination purposes.
8. ☐ Formal drawings are required in response to this Office action.
9. ☐ The corrected or substitute drawings have been received on _____. Under 37 C.F.R. 1.84 these drawings are ☐ acceptable; ☐ not acceptable (see explanation or Notice of Draftsman's Patent Drawing Review, PTO-948).
10. ☐ The proposed additional or substitute sheet(s) of drawings, filed on _____. has (have) been ☐ approved by the examiner; ☐ disapproved by the examiner (see explanation).
11. ☐ The proposed drawing correction, filed _____, has been ☐ approved; ☐ disapproved (see explanation).
12. ☐ Acknowledgement is made of the claim for priority under 35 U.S.C. 119. The certified copy has ☐ been received ☐ not been received ☐ been filed in parent application, serial no. _____; filed on _____.
13. ☐ Since this application apppears to be in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under Ex parte Quayle, 1935 C.D. 11; 453 O.G. 213.
14. ☐ Other

EXAMINER'S ACTION

The oath or declaration is defective. A new oath or declaration in compliance with 37 C.F.R. § 1.67(a) identifying this application by its Serial Number and filing date is required. See M.P.E.P. §§ 602.01 and 602.02.

The oath or declaration is defective because:

The last page is missing from the declaration filed August 17, 1992.

Claims 60-66 are rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 60-66 are indefinite in their recitation of "immunogenic polypeptide" because the metes and bounds of immunogenic polypeptide are not set forth. It would appear that in the instant claims the intent is that "immunogenic polypeptide" means a polypeptide which is recognized by an antibody whereas the person of ordinary skill in the art would understand immunogenic polypeptide to mean one which elicits an immune response.

Claims 60-66 are indefinite in their recitation of "synthetic polypeptide" because the metes and bounds of synthetic are not set forth. Presumably, synthetic is meant to mean non-naturally occurring or not made by the viral genome or recombinantly produced, however, it does not.

Claims 60-66 should also recite that the synthetic polypeptide is an HIV polypeptide.

The following is a quotation of the first paragraph of 35 U.S.C. § 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

The specification is objected to under 35 U.S.C. § 112, first paragraph, as failing to adequately teach how to make and/or use the invention, i.e. failing to provide an enabling disclosure.

Factors to be considered in determining whether a disclosure would require undue experimentation have been summarized by the board in *Ex parte Forman*, 230 USPQ 546

(Brd. Pat. App.&Int., 1986) and reiterated by the Federal Circuit (*In re Wands*, 858 F.2d 731, 8 USPQ2d 1400 (Fed. Cir. 1988)). They include (1) the quantity of experimentation necessary, (2) the amount of direction or guidance presented, (3) the presence or absence of working examples, (4) the nature of the invention, (5) the state of the prior art, (6) the relative skill of those in the art, (7) the predictability or unpredictability of the art, and (8) the breadth of the claims.

Applicants do not provide guidance as to how to produce immunogenic portions of the envelope domain of HIV. There is no description of what regions of the envelope domain contribute to its immunogenicity nor is there description of which immunogenic domains lead to the formation of antibodies in humans infected with HIV. Presentation of the sequence of the HIV genome and examples of the expression of portions of the envelope domain are insufficient to establish that untested regions or regions smaller than those exemplified would have a reasonable expectation of being immunogenic or of being recognized by antibodies present in humans infected with HIV. The exemplified domains are starting points for trying to find out if there are smaller regions therein which have the required activity.

Application SN 06/667501 sets forth the expression of the putative envelope region by COS cells infected with an expression vector containing an approximately 3300 bp KpnI-EcoRI fragment of the HIV genome. Absent a deposit of either the expression plasmid or the lambda clone from which the restriction fragment was obtained the specification is non-enabling. The recitation of the sequence of HIV in the Figures is not enabling because the Figures are informal. Expression in COS cells was detected by immunofluorescence and there is no guidance as to how to prepare the expressed protein for use in other immunoassay

formats. There is no characterization of the expressed product with regard to its molecular weight, post-translational modification, e.g. glycosylation or proteolytic cleavage, or cellular localization. Nor is it clear from the specification that the expressed material which is being recognized actually reflects recognition of envelope domains in as much as the insert contains sequences additional to the putative envelope gene. Nor does the specification set forth guidance as to what modifications to the KpnI-EcoRI fragment may be necessary in order to facilitate expression in other eukaryotic or prokaryotic expression systems.

It is apparent that the expression plasmid containing the KpnI-EcoRI fragment or the starting lambda clone is required to practice the claimed invention. As a required element it must be known and readily available to the public or obtainable by a repeatable method set forth in the specification. If it is not so obtainable or available, the enablement requirements of 35 U.S.C. §112, first paragraph, may be satisfied by a deposit of the expression plasmid containing the KpnI-EcoRI fragment or the starting lambda clone. See 37 CFR 1.802.

The specification does not provide a repeatable method for obtaining the expression plasmid containing the KpnI-EcoRI fragment or the starting lambda clone and it does not appear to be readily available material. Deposit of the expression plasmid containing the KpnI-EcoRI fragment or the starting lambda clone would satisfy the enablement requirements of 35 U.S.C. §112.

If deposits have been made under the provisions of the Budapest Treaty , filing of an affidavit or declaration by applicants, assignees or a statement by an attorney of record over his or her signature and registration number stating that each deposit has been accepted by an International Depository Authority under the provisions of the Budapest Treaty, that all restrictions upon public access to each deposits will be irrevocably removed upon the grant of a patent on this application and that each deposit will be replace if viable samples cannot be dispensed by the

depository is required. This requirement is necessary when deposits are made under the provisions of the Budapest Treaty as the Treaty leaves this specific matter to the discretion of each State. Amendment of the specification to recite the date of deposit and the complete name and address of the depository is required. As a possible means for completing the record, applicant may submit a copy of the contract with the depository for deposit and maintenance of each deposit.

If a deposit is not made under the terms of the Budapest Treaty, then an affidavit or declaration by Applicants or someone associated with the patent owner who is in a position to make such assurances, or a statement by an attorney of record over his or her signature, stating that the deposit has been made at an acceptable depository and that the following criteria have been met:

(a) during the pendency of this application, access to each deposit will be afforded to one determined by the Commissioner to be entitled thereto;

(b) all restrictions imposed by the depositor on the availability to the public of the deposited biological material will be irrevocably removed upon the granting of a patent on this application;

(c) each deposit will be maintained in a public depository for a period of at least thirty years from the date of deposit and at least five (5) years after the date of the most recent request for the furnishing of a sample of the deposited biological material;

(d) a viability statement in accordance with the provisions of 37 CFR 1.807; and

(e) the deposit will be replaced should it become necessary due to inviability, contamination or loss of capability to function in the manner described in the specification.

In addition the identifying information set forth in 37 CFR 1.809(d) should be added to the specification. See 37 CFR 1.803-37 CFR 1.809 for additional explanation of these requirements.

The specification of SN 07/138894 and its children set forth additional specific embodiments of portions of the env domain and their expression in bacteria and yeast. However, the specification does not provide guidance as to what sub-regions of the expressed domains would have a reasonable expectation of being recognized by antibodies present in the sera of patients infected with HIV.

Claims 60-66 are rejected under 35 U.S.C. § 112, first paragraph, for the reasons set forth in the objection to the specification.

The following is a quotation of the first paragraph of 35 U.S.C. § 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

The specification is objected to under 35 U.S.C. § 112, first paragraph, as the specification, as originally filed, does not provide support for the invention as is now claimed.

The specification does not set forth guidance either by way of reference or example as to how to produce the claimed immunogenic polypeptides by chemical synthesis.

Claims 60-66 are rejected under 35 U.S.C. § 112, first paragraph, for the reasons set forth in the objection to the specification.

Claims 60-66 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-22 of U.S. Patent No. 5,156,949. Although the conflicting claims are not identical, they are not patentably distinct from each other because the instantly claimed invention appears to include within its scope the specific embodiments of the claims of the patent.

The obviousness-type double patenting rejection is a judicially established doctrine based upon public policy and is primarily intended to prevent prolongation of the patent term by prohibiting claims in a second patent not patentably distinct from claims in a first patent. *In re Vogel*, 164 USPQ 619 (CCPA 1970). A timely filed terminal disclaimer in compliance with 37 C.F.R. § 1.321(b) would overcome an actual or provisional rejection on this ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 C.F.R. § 1.78(d).

The following is a quotation of the appropriate paragraphs of 35 U.S.C. § 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --
(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 60-66 are rejected under 35 U.S.C. § 102(b) as being clearly anticipated by Chang et al. (US Patent 4,774,175). See for example claims 2-15.

Claims 60-66 are rejected under 35 U.S.C. § 102(b) as being anticipated by Cosand (US Patent 4,629,783). Cosand describes peptides from the env domain of HIV and their use in solid phase immunoassays for the detection of antibodies present in the sera of patients infected with HIV.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael Woodward whose telephone number is (703) 308-3890.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Papers related to this application may be submitted to Group 180 by facsimile transmission. Papers should be faxed to Group 180 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15,1989).

The CM1 Fax Center number is (703) 305-3014.

MICHAEL P. WOODWARD
PATENT EXAMINER
GROUP 1800

Michael P. Woodward
June 12, 1994